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reaching a conclusion on this equitable defense.

Sun Life of Canada next alleges that Sun America should be estopped from contesting the use of SUN LIFE (U.S.) because Sun America implicitly acquiesced to the use of SUN Life (U.S.) by acting as an agent of Sun Life of Canada and selling Sun Life of Canada's products under the name SUN LIFE (U.S.). Put another way, Sun Life of Canada contends that by selling products designated by SUN LIFE (U.S.), Sun America implicitly consented to Sun Life of Canada's use of that specific mark (even if potentially confusing). To establish this acquiescence defense, Sun Life of Canada would need to establish the three elements identified above: active representation, inexcusable delay, and undue prejudice. *See supra* slip op. at _____. I note for the district court that an "active representation" need not come via a "specific endorsement" or formal agreement, *see R15-137-16*; rather, implied acquiescence may be inferred from a clear encouragement of the use of the allegedly infringing mark, as when, for example, the plaintiff substantially contributes to the marketing of the allegedly infringing products. *See, e.g., Coach House*, 934 F.2d at 1563-64; *ConAgra*, 743 F.2d at 1516-18; *Land O'Lakes, Inc. v. Land O'Frost, Inc.*, 224 U.S.P.Q. 1022, 1029-30 (TTAB 1984); *Hitachi Metals Int'l v. Yamakyu Chain Kabushiki*, 209 U.S.P.Q. 1057, 1067 (TTAB 1981). Once again, in deciding this issue, the district court should carefully consider Sun America's proffered reasons for its alleged acquiescence and delay. *See supra* slip op. at _____.
_____.

IV.

Sun America has described this case as "open-and-shut" because Sun Life of Canada has allegedly used an identical mark for competitive products. *See Appellees' Br. at 4 n.2* (citing 2 J. Thomas McCarthy, *Trademarks and Unfair Competition* § 23:3, at 56 (2d ed. 1984)). As evidenced by my discussion, I am unpersuaded as to that conclusion. This case has a complex and unique history that spans over 100 years. Both parties to this dispute have persuasive claims, counter-claims, and defenses. All are interrelated. All require not only a careful analysis of each party's trademarks, products, markets, clients, and distribution channels, but also an analysis of how circumstances may have changed over time. Arguably, in this case, convergence has created competition and confusion. Only precise, step-by-step de-

tailed analysis can illuminate an appropriate resolution that is capable of meaningful appellate review. To suggest otherwise ignores the complexity and subtlety presented in this case.

U.S. Patent and Trademark Office Board of Patent Appeals and Interference

Staehelin v. Secher

No. 101,597

Decided September 28, 1992

Released October 8, 1992

PATENTS

1. Practice and procedure in Patent and Trademark Office — Interference — Burden of proof (§110.1707)

Patentability/Validity — Specification — Enablement (§115.1105)

Moving party in interference proceeding ordinarily bears burden of proof; thus, party moving for judgment on grounds that opposing party's claims corresponding to count are unpatentable because opposing party's earlier filed British application does not meet requirements of 35 USC 112, first paragraph, bears burden of making out *prima facie* case of non-enablement.

2. Patentability/Validity — Specification — Enablement (§115.1105)

Specification, in order to satisfy enablement requirement under 35 USC 112, first paragraph, need not be "blueprint" which, if followed, would unfailingly reproduce exactly applicant's claimed invention; rather, only objective enablement without resort to undue experimentation is required, and thus party in interference which claims that disclosure is non-enabling but which has failed to present persuasive, objective evidence that, at time invention was made, undue experimentation would have been required by those skilled in art in order to practice invention, has failed to meet its burden of making out *prima facie* case of non-enablement.

3. Patentability/Validity — Specification — Written description (§115.1103)

Function of "written description" requirement of 35 USC 112, first paragraph, is to ensure that applicant had possession, as of filing date of application relied upon, of subject matter later claimed by applicant:

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inquiry into satisfaction of written description requirement is factual, depending on nature of invention and amount of knowledge imparted by disclosure to those skilled in art.

4. Practice and procedure in Patent and Trademark Office — Interference — Pleadings and submissions (§110.1706)

Patentability/Validity — Specification — Best mode (§115.1107)

Board of Patent Appeals and Interferences will not consider assertion, by party in interference, that opposing party's disclosure failed to satisfy best mode requirement of 35 USC 112, first paragraph, since party's motion for judgment on grounds that opposing party's claims were unpatentable failed to include any argument or evidence concerning best mode, but rather such best mode arguments were raised for first time in party's brief at final hearing.

5. Patentability/Validity — Date of invention — In general (§115.0401)

Party in interference which conceived its invention in Switzerland may not rely on evidence of such conception for purposes of proving priority, but may still be awarded priority if it demonstrates, by preponderance of evidence, an introduction of conception into U.S. prior to opposing party's constructive reduction to practice, coupled with reasonable diligence from time period just prior to opposing party's entry into field up to its reduction to practice.

6. Patentability/Validity — Date of invention — Conception (§115.0403)

Evidence of conception which names only one of actual inventive entity inures to benefit of, and serves as evidence of conception by, complete inventive entity.

7. Patentability/Validity — Date of invention — Reduction to practice (§115.0405)

Receipt in U.S. of nine monoclonal antibodies, along with explanatory letter characterizing nature of monoclonal antibodies, does not constitute introduction of actual reduction of subject matter of count into U.S., without any evidence showing that compound introduced into U.S. and identified as compound within count was subjected to testing in U.S.

8. Patentability/Validity — Date of invention — Diligence (§115.0409)

Activities abroad will not be considered for purposes of establishing diligence in re-

ducing invention to practice; inventor whose work, prior to introduction into U.S. of samples of monoclonal antibodies produced in Switzerland, was performed only in Switzerland cannot rely on such activity to establish date of invention.

Particular patents — Chemical — Monoclonal antibodies

4,423,147, Secher and Burke, monoclonal antibody to interferon- α , inventors held entitled, in interference, to patent containing claims 1 through 7.

Patent interference between application of Theophil Staehelin, Christian Stahli, and Vicenzo Miggiano, serial no. 06/612,762, filed May 22, 1984, accorded benefit of serial no. 07/351,282, filed Feb. 22, 1982, and Swiss application nos. 7773/81, filed Dec. 4, 1981, and 1343/81, filed Feb. 27, 1981, and patent granted to David S. Secher and Derek C. Burke on Dec. 27, 1983, patent no. 4,423,147, serial no. 06/333,856, filed Dec. 10, 1981, accorded benefit of U.K. application nos. 8012096, filed April 11, 1980, 035884, filed Nov. 7, 1980, and PCT application No. GB81/00067, filed April 13, 1981 (antibodies against proteins). Senior party Secher and Burke held entitled to their patent containing claims 1 through 7 corresponding to the count.

William H. Epstein, John S. Saxe, Bernard S. Leon, George M. Gould, William G. Isgro, Peter R. Shearer, and Steve T. Zel-son, Nutley, N.J., and William H. Vogt, III, David R. Plautz, and Stephen M. Haracz, White Plains, N.Y., for Staehelin, et al.

Watson T. Scott, John W. Malley, Paul N. Kokulis, Allen Kirkpatrick, David E. Varner, Lloyd J. Street, George T. Mo-bille, James L. Dooley, Alvin Gutttag, Raymond F. Lippitt, G. Lloyd Knight, Carl G. Love, Lawrence A. Hymo, Akin T. Davis, Edgar H. Martin, William K. West, Jr., Kevin E. Joyce, Edward M. Prince, Donald B. Deaver, David W. Brinkman, George M. Sirilla, William T. Bullinger, Donald J. Bird, Larry S. Nixon, James R. Longacre, Arthur R. Crawford, W. Warren Taltavull, Michael L. Keller, Charles R. Donohoe, Sherman O. Parrett, and Robert A. Vanderhye, Washington, D.C., for Secher, et al.

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Before Sofocleous, Downey, and Metz, examiners-in-chief.

Metz, examiner-in-chief.

This interference involves an application of Staehelin et al. assigned to Hoffman-LaRoche Inc. and a patent of Secher et al. which is unassigned according to the records of the Patent and Trademark Office.

The subject matter at issue relates to a monoclonal antibody produced by a murine derived hybrid cell line wherein the antibody is capable of specifically binding to at least one antigenic determinant of interferon- α ¹. The sole count at issue corresponds exactly to claim 1 of the Secher et al. (Secher) patent and reads as follows:

Count 1

A monoclonal antibody produced by a murine derived hybrid cell line wherein the antibody is capable of specifically binding to at least one antigenic determinant of interferon- α .

The claims of the parties which have been designated as corresponding to the count are:

Staehelin et al. Claims 10-12, 14,
16-21 and 23-25

Secher et al. Claims 1-7

Both parties requested a testimony period. Staehelin et al. (Staehelin) requested a rebuttal testimony period. Both parties presented testimony, affidavits and associated exhibits in support of their respective positions.³ Both parties filed briefs. Staehelin filed a reply brief. Both parties were represented by their respective legal representatives at final hearing. No issue of interference-in-fact was raised.

The issues presented for decision by the Board of Patent Appeals and Interferences are: 1) the propriety of the Examiner-in-

¹ Interferon- α is produced by leukocyte cells and is, therefore, also known as leukocyte interferon. See StaX 55, column 2, lines 21 through 23.

References to the Staehelin brief will be designated by StaB, followed by the page number. References to the Staehelin reply brief will be designated by StaRB, followed by the page number. References to the Staehelin record will be designated StaR, followed by the page number. References to the Staehelin exhibits and cross exhibits will be designated by StaX and StaCX, respectively, followed by the exhibit number. References to the Secher et al. (Secher) brief will be designated SB, followed by the page number. References to the Secher record will be designated SR, followed by the page number. References to the Secher exhibits will be designated by SX, followed by the exhibit number.

Chief's (EIC's) denial of Staehelin's preliminary motion for judgment on the ground that Secher's claims are unpatentable for failure to comply with 35 USC 112, paragraph 1, as lacking an adequate "written description" of the genus embraced by Secher's claims corresponding to the count and as being based on a non-enabling disclosure, in light of newly presented evidence adduced from the parties' testimony³; 2) the propriety of the EIC's denial of Staehelin's motion for judgment on the grounds that Secher's claims corresponding to the count are unpatentable under 35 USC 102 and 35 USC 103; 3) the propriety of the EIC's denial of Secher's preliminary motion for judgment on the grounds that Staehelin's claims corresponding to the count are unpatentable under 35 USC 102 and 35 USC 103; 4) the propriety of the EIC's granting Secher's motion for benefit of their earlier filed British applications; 5) priority of invention; and, 6) Secher's motion under 37 CFR 1.656(h) to suppress certain evidence proffered from Staehelin's testimony.

THE DECISION ON PRELIMINARY MOTIONS

In Paper Number 45, mailed on May 28, 1987, the EIC: denied both of Staehelin's motions for judgment; denied Secher's motions for judgment; denied Secher's motion to deny Staehelin benefit of their earlier filed Swiss applications; dismissed without prejudice Secher's motion for judgment on the ground that Staehelin's claims are unpatentable for inequitable conduct; and, granted Secher's motion for the benefit of their earlier filed British applications. In view of the granting of Secher's motion for benefit, the order of the parties was reversed.

Staehelin requested reconsideration of the EIC's granting of Secher's motion for benefit of its earlier filed British applications in Paper Number 46 and, on June 23, 1987, a panel of this Board denied Staehelin's request for reconsideration after concluding

³ Ordinarily, preliminary motions should be supported by facts which would justify granting the motion, 37 CFR 1.639(a). It is not appropriate to file a motion, see if the motion will be granted, and then ask for testimony only after the motion is denied. *Hanagan v. Kimura*, 16 USPQ2d 1791 (Comm'r. 1990), *Orikasa v. Ooniishi*, 10 USPQ2d 1996, n.12 (Comm'r. 1989). However, given the state of the law at the time the parties requested testimony and because the EIC granted the parties a testimony period, in this instance, we will consider the parties' additional evidence adduced in the testimony period.

that the EIC properly granted Staehelin's motion for benefit (Paper Number 47).

THE COUNT

It is by now well-settled that, absent ambiguity, a count in an interference is to be given the broadest, reasonable interpretation that the language of the count permits without resort to either party's disclosure. *DeGeorge v. Bernier*, 768 F.2d 1318, 226 USPQ 758 (Fed. Cir. 1985); *Fontijn v. Okamoto*, 518 F.2d 610, 186 USPQ 97 (CCPA 1975); *Lamont v. Berguer*, 7 USPQ2d 1580 (BPAI 1988). Accordingly, we construe the subject matter defined by the count in this interference as being directed to any monoclonal antibody (MAB) produced by a hybridoma derived from a mouse which MAB binds to at least one antigenic determinant of interferon- α in any amount or to any degree.

OPINION (Issues 1) and 2)

Staehelin's motions for judgment were based on the grounds that Secher's earlier filed British applications did not meet the requirements of 35 USC 112, first paragraph with respect to enablement and written description for the subject matter claimed by Secher in its later filed U.S. application, and, in part, on the grounds that certain references which were published after the filing date of Secher's earlier filed British applications, but before Secher's U.S. filing date, were "prior art" with respect to the subject matter claimed in Secher's U.S. application which "prior art" rendered the claims therein unpatentable under 35 USC 102 and 35 USC 103.

The question of whether or not references which "intervened" between the filing date of Secher's British applications whose benefit had been sought under 35 USC 119 and the filing date of Secher's later filed U.S. application depends on whether Secher's earlier filed British applications support, within the meaning of section 112, first paragraph, what is claimed in Secher's U.S. application. *In re Gostelli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989). Thus, the ultimate resolution of the issues delineated as 1) and 2), above, necessarily depends on whether or not Secher's earliest filed British Application No. 8012096 (British I) complies with the requirements of 35 USC 112 implicit in 35 USC 119.⁴

⁴ *Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973).

Issue 1) — Enablement of Secher's Involved Patent Disclosure

[1] We begin by noting the fundamental precept that the moving party ordinarily bears the burden of proof. See *Weil v. Fritz*, 601 F.2d 551, 202 USPQ 447 (CCPA 1979), especially the cases cited at 601 F.2d 555, 202 USPQ 450 [1], and 37 CFR 1.637(a). Thus, Staehelin, as the party moving for judgment on the grounds that Secher's claims corresponding to the count are unpatentable because Secher's British I does not meet the requirements of 35 USC 112, first paragraph, bears the burden of making out a *prima facie* case of nonenablement. This Staehelin has failed to do.

It has been consistently held that the first paragraph of 35 USC 112 requires nothing more than objective enablement. *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). In satisfying the enablement requirement, an application need not teach, and preferably omits, that which is well-known in the art. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986); *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). How such a teaching is set forth, whether by the use of illustrative examples or by broad descriptive terminology, is of no importance since a specification which teaches how to make and use the invention in terms which correspond in scope to the claims *must* be taken as complying with the first paragraph of 35 USC 112 *unless* there is reason to doubt the objective truth of the statements relied upon therein for enabling support. *Marzocchi* at 439 F.2d 223, 169 USPQ 369.

[2] The error we see in Staehelin's approach to the question before us is that Staehelin would require a patent specification to be a blueprint which, if followed, would unfailingly reproduce exactly an applicant's claimed invention. However, the law does not require a specification to be a blueprint in order to satisfy the requirement for enablement under 35 USC 112, first paragraph. In *In re Gay*, 309 F.2d 769, 135 USPQ 311 (CCPA 1962), Judge Rich noted at 309 F.2d 316, 135 USPQ 316 that in satisfying the "enablement" requirement of 35 USC 112:

... Not every last detail is to be described, else patent specifications would turn into production specifications, which they were never intended to be.

Further, as the court in *Hybritech* noted at 802 F.2d 1384, 231 USPQ 94:

Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention, . . . is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive, . . . and is determined as of the filing date of the patent application. . . . (citations omitted).

During the preliminary motions stage of this interference, Staehelin failed to present persuasive, objective evidence that at the time the invention of Secher was made *undue* experimentation would have been required by those skilled in the art to practice Secher's invention. On the other hand, Secher relied on the declaration testimony of Caesar Milstein, Nobel laureate and coauthor of the seminal work in MAB's (Kohler, G. and Milstein, C., *Nature*, (1975) 256, 495-497, SB, page 15), to the effect that he found the Secher disclosure to be enabling, that Staehelin's position was founded on a "misunderstanding of the science involved", and that the procedure set out in *Nature* (StaX 58) "enables the identification of any antibody binding to interferon- α with sufficient affinity to coprecipitate interferon- α ." (Milstein declaration, Paper Number 27, Paragraphs 5 and 7, respectively). Further, as the discussion immediately below will indicate, our reviewing court and this Board have concluded that the preparation and isolation of MAB's to a wide variety of antigens was well-known in the art in April 1980 at the time Secher's invention was made.

Our reviewing court in *Hybritech* noted in discussing the quality of the patent-in-suit's enabling disclosure at 802 F.2d 1384, 231 USPQ 94 that:

The record fully supports the '110 patent's statement that

The monoclonal antibodies used for the present invention are obtained by the [hybridoma] process discussed by Milstein and Kohler. . . . The details of this process are well known and not repeated here.

We note that the patent-in-suit in *Hybritech* was filed on August 4, 1980 and thus, was filed after Secher's U.S. application was filed. Nonetheless, the article by Kohler and Milstein was published in 1975. In discussing the state of the art of the screening step of Kohler and Milstein's seminal work, the court continued at 802 F.2d 1384, 231 USPQ 94 that:

With respect to screening, the only permissible view of the evidence is that screening methods used to identify the necessary characteristics, including affinity, of the monoclonal antibodies used in

the invention were known in the art and that the '110 patent contemplated one of those. At trial, Monoclonal's counsel stated "it is a procedure that was known in '78".

In *Ex parte Erlich*, 3 USPQ2d 1011, 1014 (BPAI 1987), this Board, in discussing the state of the art of preparing MAB's to human fibroblast interferon in an application for patent filed in November 1981, noted with respect to the screening of the hybridomas for MAB production that:

... the record is clear that one of ordinary skill in the art may screen the hybridomas produced in the present invention for monoclonal antibody production using other, well known assays:

The Board in *Erlich* continued at 3 USPQ2d 1015 that:

We find that the claims on appeal differ from the above described prior art only in the use of human fibroblast interferon as the starting antigen in immunizing the animal. However, it is our finding that once the antigen of interest is selected, the use of that antigen in the known method of Kohler and Milstein will result in the expected hybrid cell lines and the specific monoclonal antibodies.

Thus, the reference to Kohler and Milstein evidences that the technology discussed was well-known in the relevant time period, that is, April 1980. Indeed, the Board in *Erlich*, at 1015 discussed the Secher *Nature* article (StaX 58) here in issue, noting:

The level of skill in this art is adequately represented by the Secher publication which shows that the basic method of Kohler and Milstein may be readily used and adapted for various antigens such as an interferon. (emphasis added).

In discussing the conventionality of screening hybridomas for antibody production, the Board in *Erlich*, at page 1016, found that:

... The obtention of a large number of hybrid cells at the fusion step and the necessity of screening them for the desired antibody production has been routine in this art since the work of Kohler and Milstein. (emphasis added).

To the extent Staehelin have relied on *Ex parte Old*, 229 USPQ 196 (BPAI, 1985) for the proposition that the obtention of MAB's was recognized as "unpredictable" in 1980, we simply note that the Board in *Erlich* distinguished *Old* from the case before it based on their facts available in *Erlich* but not available in *Old*.

In *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court, in discussing the question of enablement raised by the

disclosure of the application in issue, noted at 858 F.2d 736, 737, 8 USPQ2d 1404 that:

Enablement is not precluded by the necessity for some experimentation such as routine screening.

The court then went on to analyze the factors to be considered in determining whether a disclosure would require undue experimentation and ultimately concluded that the Wands application, which was filed in September 1980, was based on an enabling disclosure which did not require undue experimentation.

At 858 F.2d 740, 8 USPQ2d 1406, the court found that:

... The record indicates that cell fusion is a technique that is well known to those of ordinary skill in the monoclonal antibody art, and there has been no claim that the fusion step should be more difficult or unreliable where the antigen is HBsAg than it would for other antigens.

and that:

... There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.

and additionally that:

... Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody.

Ultimately, the court concluded that:

... Furthermore, in the monoclonal antibody art it appears that an "experiment" is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen. This process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics.

The technology discussed by the Wands court above was obviously the technology described originally by Kohler and Milstein in 1975.

Additionally, there is testimony in the record from Dr. Pestka indicating that the procedures used by Staehelin were within the ordinary skill of the routine in the art in 1979. Specifically, at StaR, page 324, paragraph 8, Dr. Pestka noted that:

During his January 1979 visit, Dr. Staehelin and I discussed the collaborative research effort for obtaining leukocyte interferon. As part of that research collaboration Dr. Staehelin indicated to me that his laboratory in Roche-Basle would prepare monoclonal antibodies

against leukocyte interferon by conventional hybridoma technology ...

In light of the various quotes from the decisions noted above, we conclude that the "conventional hybridoma technology" referred to by Dr. Pestka included the technology of Kohler and Milstein and, therefore, that the technology was also well-known at the time Secher's invention was made in 1980.

Accordingly, we conclude that Staehelin have failed to meet their burden of making out a *prima facie* case of non-enablement. In so-concluding, we have not overlooked the testimony of Staehelin's various experts, which testimony reaches the conclusion opposite from our own on this issue. However, we are convinced that Staehelin's experts, like Staehelin, applied an improper standard to Secher's disclosure in measuring what Secher's disclosure fairly taught the person of ordinary skill in the MAB art in 1980. Representative of the improper standard applied by Staehelin's experts is the testimony of Dr. Eisen at StaR, page 499 wherein he stated:

If Dr. Secher were to repeat it exactly as he had carried it out in *Nature* [British I], the same antigenic preparation used for immunization and screening, since he got one monoclonal antibody out of the procedure I think there is a good chance he would get another one *but not a certainty*. On the other hand, if I were to repeat it, based on the information in there, I would not feel that my prospects would be — let me put it this way — *I think anybody else repeating it could not be assured of obtaining the same kind of results.* (emphasis added)

As we have stated above, the enablement requirement does not require exact reproduction of the results obtained by Secher in British I, only objective enablement without resort to undue experimentation is required. Moreover, Secher's experts presented countervailing testimony which reached the opposite conclusion from Staehelin's experts' conclusions. Thus, on balance, the additional evidence adduced by the parties' experts does not mandate any change in the EIC's conclusions below denying Staehelin's motions for judgment on the grounds that Secher's claims are unpatentable under 35 USC 112, first paragraph.

To the extent that Staehelin relies on the decision in *Wands, supra*, for the proposition that the court held Wands' disclosure to be representative of the type of disclosure required by 35 USC 112, first paragraph, we simply note that there is no such holding in the case. Rather, the court simply held that the disclosure, held to be inadequate by the

Board of Patent Appeals and Interferences for lack of enablement for failure to deposit what the Board considered to be an essential microorganism and as requiring undue experimentation, was enabling in view of the state of the art at the time Wands' invention was made and in view of the high level of skill of the routineer in the art at the time Wands' invention was made. Staehelin has failed to direct our attention to that portion of the decision in *Wands* which stands for the proposition that the court considered the Wands' disclosure the minimum disclosure required to meet the requirements of 35 USC 112, first paragraph.

We reject Staehelin's attempt to discredit Dr. Novick's testimony because she had obtained her Ph.D. in 1979, about the time Secher's invention was made. As the Board held in *Ex parte Hiyamizu*, 10 USPQ2d 1393 (BPAI 1988) with respect to the hypothetical person of ordinary skill in the art:

... It is our view that such a hypothetical person is no more definable by way of credentials than is the hypothetical "reasonably prudent man" standard found in laws pertaining to negligence.

Accordingly, we have considered Dr. Novick's testimony in the context of testimony from an expert, just as we have considered Dr. Eisen's testimony, based on each witness' education, professional training, professional experience and credentials. To the extent Staehelin's experts have given a basis in the evidence for their opinions⁵, we do not consider that the evidence adduced from their testimony overcomes the equally persuasive evidence adduced from Secher's experts.

Issue 1) — Written Description of Secher's Patent Disclosure

Staehelin's attack on the disclosure in Secher's British I as failing to meet the written description requirement of 35 USC 112, first paragraph, does not withstand analysis. Staehelin has failed to discharge its burden of proving that British I does not "describe" the subject matter later claimed by Secher in its U.S. application. *Wagoner v. Barger*, 463 F.2d 1377, 175 USPQ 85 (CCPA 1972).

⁵ Even the opinion of experts must find a foundation in the evidence. *Cable Electric Products, Inc. v. Genmark, Inc.*, 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985); *In re Grunwell*, 609 F.2d 486, 203 USPQ 1055 (CCPA 1979); *In re Warner*, 379 F.2d 1011, 154 USPQ 173 (CCPA 1967).

An earlier filed foreign patent application must comply with the requirements of 35 USC 112, first paragraph, if the later filed U.S. application claiming the same invention as in the foreign application is to be accorded benefit under 35 USC 119. *Vogel v. Jones*, 486 F.2d 1068, 179 USPQ 425 (CCPA 1973); *Kawai v. Metlesics*, *supra*. The written description requirement of 35 USC 112, first paragraph, is separate from the enablement requirement found in the same provision of 35 USC 112. *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984).

[3] The function of the "written description" requirement of 35 USC 112, first paragraph, is to ensure that applicants had possession, as of the filing date of the application relied on, of the subject matter later claimed by them. *In re Blaser*, 556 F.2d 534, 194 USPQ 122 (CCPA 1977). The inquiry into satisfaction of the written description requirement is factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. *In re Wertheim*, 646 F.2d 527, 191 USPQ 90 (CCPA 1976). Satisfaction of the "written description" requirement does not require *in haec verba* antecedence in the originally filed application. *In re Lukach*, 440 F.2d 1263, 169 USPQ 795 (CCPA 1971). The question is whether one following applicant's specification would necessarily select the later claimed subject matter. *Freerksen v. Gass*, 21 USPQ2d 2007 (BPAI 1990). The question, therefore, is whether the originally filed application would have reasonably conveyed to a person of ordinary skill in the art that applicants invented the subject matter later claimed by them including the limitations in question. *In re Smythe*, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973).

Page 1 of the British I application⁶ discloses:

In this paper we describe the properties of a *monoclonal antibody* to an antigen not available in pure form for screening assays and present in immunizing material at a concentration of 0.1-1% of the total protein injected. The antigen is *human leukocyte interferon*, a protein (or group of proteins) that confers antiviral protection on human cells *in vitro* and *in vivo*. (emphasis added)

Further, at page 2, British I discloses:

We report here the *isolation of a hybrid myeloma, secreting antibody to human*

⁶ The parties agree that the British I application corresponds exactly to the *Nature* article, StaX 58. (StaB, page 8; SB, pages 4 and 16).

leukocyte interferon, and show that this antibody can be used for the purification of interferon by immunoadsorption. (emphasis added)

At page 3, the specification discloses immunizations utilizing mice. Thus, we conclude that Secher's disclosure in British I would have reasonably conveyed to a person possessing ordinary skill in the art that Secher possessed the genus later claimed by them in their U.S. application in the sense of 35 USC 112, first paragraph. That is, British I describes a monoclonal antibody, produced by a hybridoma derived from a mouse and which monoclonal antibody is "capable of specifically binding to at least one antigenic determinant of interferon- α ".

To the extent Staehelin's argument that the disclosure in British I is inadequate because the specification does not describe the exact details for preparing every species within the genus described, we note that the law does not require such exemplification or detail. Compare *Utter v. Hiraga*, 845 F.2d 993, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988). Staehelin's position on Secher's written description for its claims which correspond to the count appears to parallel the position enunciated by the court in *Kennecott v. Kyocera*, 835 F.2d 1419, 5 USPQ2d 1194 (Fed. Cir. 1987) wherein the court stated at 835 F.2d 1421, 5 USPQ2d 1197 that:

... The purpose of the description requirement of this paragraph [35 USC 112, first paragraph] is to state what is needed to fulfill the enablement criteria. These requirements may be viewed separately, but they are intertwined.

However, in *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991), the court noted at 935 F.2d 1563, 1564, 19 USPQ2d 1117 that:

To the extent that *Kennecott* conflicts with *Wilder*, we note that decisions of a three-judge panel of this court cannot overturn precedential decisions. ... This court in *Wilder* (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 USC 112, first paragraph, requires a "written description of the invention" which is separate and distinct from the enablement requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed. (citations omitted)

Therefore, based on all of the above, we conclude that Staehelin has failed to meet its burden of proving that British I fails to comply with the "written description" requirement of the first paragraph of 35 USC 112.

Issue 1) — Best Mode Disclosed in Secher's Patent

[4] Staehelin's motion for judgment on the grounds that Secher's claims were unpatentable under 35 USC 112, first paragraph, did not include any argument or evidence that the alleged unpatentability was founded on a failure to satisfy the "best mode" requirement of the first paragraph. Accordingly, we will not now consider Staehelin's arguments concerning the alleged failure of Secher's disclosure to satisfy the "best mode" requirements of the first paragraph of 35 USC 112 raised for the first time in this interference in Staehelin's brief at final hearing. 37 CFR 1.655(b).

Issue 4) — Secher's Motion for Benefit

We conclude that Secher's motion for benefit under 35 USC 119 was properly granted. Indeed, to be accorded benefit for priority purposes, Secher's British I need only have disclosed an embodiment (species) within the subject matter of the generic count to serve as a prior constructive reduction to practice. *Squires v. Corbett*, 560 F.2d 424, 194 USPQ 513 (CCPA 1977); *Hunt v. Treppschuh*, 523 F.2d 1386, 187 USPQ 426 (CCPA 1975); *Kawai v. Metlesics, supra*. The example in British I is a species within the subject matter of the count and thus serves as a constructive reduction to practice.

Issue 2) — Staehelin's Motion for Judgment

Since we have concluded that British I satisfies the requirements of 35 USC 112, first paragraph, and since we have concluded that Secher was properly accorded benefit of British I for priority purposes, none of the references denominated as "prior art" (references 3) through 6) in Staehelin's motion for judgment, Paper Number 13) are, in fact, "prior art" with respect to Secher and, therefore the motion was and is properly denied based on those references. With respect to the references denominated as 1) and 2) in the motion for judgment, although Staehelin states in its brief at page 39 that Staehelin "renew at Final Hearing its Paper No. 13 motion for judgment". Staehelin has not specifically argued that there is any new

evidence not available during the motions period which requires overturning the presumptively correct decision by the EIC, 37 CFR 1.655(a), that references 1) and 2) neither anticipated (35 USC 102) nor rendered obvious (35 USC 103) Secher's claims corresponding to the count. Indeed, Staehelin has failed to even mention references 1) and 2) in its brief or reply brief as references 1) and 2) relate to the motion for judgment. Accordingly, we conclude that Staehelin's motion for judgment based on references 1) and 2) was and is properly denied.

Issue 3) — Secher's Motion for Judgment

Secher's motion for judgment (Paper Number 18) is said by Secher to be renewed in its brief (SB, the paragraph bridging pages 62 and 63). However, the decision by the EIC below in denying said motion is presumptively correct, 37 CFR 1.655(a). Nothing in Secher's brief overcomes the presumption of correctness accorded the EIC's decision below. Indeed, the "renewed" motion appears to be little more than a reargument of the arguments made in the motion for judgment and are based on Secher's "renewed" arguments to deny Staehelin benefit of its Swiss priority applications (SB, page 62, last full paragraph). Suffice it to say that there is nothing in the way of newly presented evidence or argument which would require that we overturn the EIC's presumptively correct decision in granting Staehelin's motion for benefit.

Issue 5) — PRIORITY

As a result of the granting of Secher's motion for benefit of their earlier filed British applications, Staehelin, as the junior party whose application was copending with Secher's application which matured into U.S. Patent Number 4,423,147, bears the burden of proving its case for priority by a preponderance of the evidence. *Morgan v. Hirsch*, 728 F.2d 1449, 221 USPQ 193 (Fed. Cir. 1984); *Peeler v. Miller*, 535 F.2d 647, 190 USPQ 117 (CCPA 1976).

In order to be awarded priority in this interference, Staehelin must prove an actual reduction to practice prior to April 11, 1980, Secher's constructive reduction to practice, or prove a conception of the subject matter of the count before Secher's effective filing date of April 11, 1980, coupled with reasonable diligence just prior to April 11, 1980, up to a reduction to practice (constructive or actual) by Staehelin. *Jepson v. Egly*, 231 F.2d 947, 109 USPQ 354 (CCPA 1956); *Hull v. Davenport*, 24 CCPA (Patents)

1116, 90 F.2d 103, 33 USPQ 506; *Wilson v. Sherts*, 21 F.2d 1070, 28 USPQ 379 (CCPA 1936).

CONCEPTION

[5] Staehelin conceived of its invention in Switzerland (StaR, ¶6, StaB, pages 11 and 46) and, therefore, may not rely on evidence of such conception for purposes of proving priority. 35 USC 104, first sentence. However, Staehelin may still be awarded priority by proving by a preponderance of the evidence an introduction of conception into the United States prior to Secher's constructive reduction to practice coupled with reasonable diligence from a time period just prior to Secher's entry into the field up to a reduction to practice by Staehelin. *Shurie v. Richmond*, 699 F.2d 1156, 216 USPQ 1042 (Fed. Cir. 1983) and *Breuer v. DeMarinis*, 558 F.2d 22, 194 USPQ 308 (CCPA 1977).

Staehelin urges in its brief that introduction of conception into the United States prior to April 11, 1980, the date of Secher's constructive reduction to practice, occurred in January 1979. Specifically, Staehelin urges that Dr. Staehelin disclosed his conception of the subject matter of the count to Dr. Pestka during Dr. Staehelin's visit to the Nutley, New Jersey facility of Hoffman-La Roche in January 1979. Evidence of introduction of conception is said to be found at StaR, page 2, ¶'s 6, 8 and 9 and StaR, page 324, ¶'s 7 and 8 (StaB, page 46). The "evidence" at StaR, page 2, ¶'s 6, 8 and 9 is the uncorroborated testimony of Dr. Staehelin, one of the coinventors, and relates to activity in Switzerland and, thus, may not be relied on as evidence of introduction of conception. 35 USC 104; *Gould v. Schawlow*, 363 F.2d 968, 150 USPQ 634 (CCPA 1966). However, the evidence at StaR page 324, ¶'s 7 and 8, is the testimony of Dr. Pestka wherein he recalled what Dr. Staehelin and he had discussed during Dr. Staehelin's January 1979 visit.

Paragraph 8 of the cited testimony from StaR, page 324 sets forth the specifics of Dr. Pestka's recollections. Therein, Dr. Pestka revealed that he and Dr. Staehelin discussed a collaborative research effort for obtaining leukocyte interferon (interferon- α). Dr. Pestka testified that Dr. Staehelin's contribution would be the preparation of MAB's against leukocyte interferon by "conventional hybridoma technology". Dr. Pestka additionally testified that he undertook to supply the leukocyte interferon to Dr. Staehelin which was necessary for immunizing the mice as the first step in obtaining hybridoma

cell lines (StaR, ¶8, page 325). Accordingly, we consider that Dr. Pestka's testimony establishes introduction of conception by Staehelin into this country sometime after January 9, 1979 (the date Dr. Staehelin's visit was to begin, StaX 30) and before January 26, 1979, the date Dr. Pestka received a letter from Dr. Staehelin in Switzerland (StaX 4).

We have not overlooked Secher's argument in its brief that Dr. Pestka's testimony cannot be considered to support a finding that conception was introduced into the United States because "the testimony of Dr. Pestka (StaR 324-349) is devoid of any evidence that the information provided to Dr. Pestka by Dr. Staehelin was sufficient to enable him to reproduce the work and obtain the invention defined by the Count herein." (SB, page 64). Nonetheless, the testimony of Dr. Pestka indicates that Dr. Staehelin's lab was working on preparing MAB's to leukocyte interferon by "conventional hybridoma technology". By now it should be abundantly clear that "conventional hybridoma technology" included the technology of Kohler and Milstein.

Lest there be any doubt of how Dr. Staehelin's lab was preparing the hybridomas, we have Dr. Pestka's testimony that he (Dr. Pestka) "undertook to supply leukocyte interferon prepared at Nutley to Dr. Staehelin for his use in immunizing mice . . ." (StaR, page 325). Clearly, the leukocyte interferon was to be used as the antigen for inducing the immune response in the mice, which mice would be sacrificed to obtain their spleen cells for fusion with the myeloma cells to obtain the hybridomas.

[6] Neither have we overlooked Secher's argument that the introduction of conception was by only one of the named inventors and, thus, could not serve as evidence of introduction of conception. However, it has been held that evidence of conception naming only one of the actual inventive entity inures to the benefit of and serves as evidence of conception by the complete inventive entity. *Haskell v. Colebourne*, 671 F.2d 1362, 213 USPQ 192 (CCPA 1982).

REDUCTION TO PRACTICE

Staehelin asserts that it introduced an actual reduction to practice of the subject matter of the count into the United States on May 22, 1980 when Dr. Staehelin sent to Dr. Pestka nine of eleven MAB's Dr. Staehelin had produced from mouse hybridomas and as evidenced by Dr. Pestka's testimony at StaR, pages 331 and 332, and ¶'s 32 through

34 and StaX 19. *Shurie v. Richmond; Breuer v. DeMarinis*; *supra*.

StaX 19 is a two-page letter from Dr. Staehelin to Dr. Pestka dated May 13, 1980 and which bears a receipt stamp indicating "RECEIVED MAY 22 1980 S. PESTKA". The letter has attached thereto two sheets, StaX 19A and StaX 19B. StaX 19A is a summary sheet outlining "the most important characteristics" of the eleven MAB's discussed in the letter. StaX 19B is a "representative neutralization experiment" wherein one of the MAB's ability to inhibit the antiviral activity of leukocyte interferon was determined.

Staehelin also asserts that Drs. Staehelin and Pestka reduced to practice the subject matter of the count in early June 1980 when Dr. Staehelin was again visiting Dr. Pestka at his lab in New Jersey when he and Dr. Pestka ran a series of immunoassays for interferon- α using the MAB's designated as LI-1 and LI-9 in Dr. Staehelin's letter of May 13, 1980. StaB, page 47. Staehelin urges that Dr. Pestka corroborated this reduction to practice by his testimony at StaR, page 336, ¶43 and StaR, page 338, ¶47.

[7] We disagree with Staehelin that receipt in Nutley, New Jersey of the nine MAB's by Dr. Pestka along with Dr. Staehelin's explanatory letter with the attachments which characterized the nature of the MAB's constituted an introduction of an actual reduction to practice of the subject matter of the count into the United States by at least May 22, 1980. *Shurie v. Richmond* and *Breuer v. DeMarinis*, *supra*, relied on by Staehelin in support of its position do not stand for the proposition argued.

As the court in *Shurie* noted at 699 F.2d 1158, 216 USPQ 1044, "An actual reduction to practice in Canada is irrelevant in an interference proceeding concerning priority of invention." *Breuer*, concerned the burden an applicant was required to meet to make out a *prima facie* case as would entitle him to an award of priority so the interference could go forward under old Rule 204(c). The court stated at 558 F.2d 28, 194 USPQ 313, that Breuer's burden, unlike Staehelin's burden here of a preponderance of the evidence, was "merely to establish a *prima facie* case." More importantly, in *Breuer* there was evidence that the compound introduced into the United States and identified as a compound within the count was subjected to testing in the United States. See also *Micheletti v. Wignall*, 196 USPQ 858 (Bd.Pat.Int. 1976), especially at 196 USPQ 861, [4]. Accordingly, the attachments to Dr. Staehelin's letter marked as StaX 19A and StaX 19B are not admissible to "establish a date of invention".

but are only admissible as evidence to provide the identity of the MAB's introduced into this country. *Breuer v. DeMarinis, supra.*

Nonetheless, the Staehelin record also establishes that Dr.'s Staehelin and Pestka carried out various immunoassays using the MAB's introduced into the United States by Dr. Staehelin and identified by Dr. Pestka as MAB's within the count in this interference in Dr. Pestka's lab in the United States sometime between June 2, 1980 and July 23, 1980. (StaR, pages 333 through 340; StaX 20). We, therefore, agree with the conclusion implicit in Secher's argument in its brief at SB, page 66, that "until such time as Drs. Pestka and Staehelin carried out the immunoassays in June 1980, there was no evidence or assurance that the materials in hand would bind to antigenic determinants of human interferon- α ," and that some evidence of activity in the United States establishing utility for the MAB's introduced and identified was required to establish an actual reduction to practice.

We conclude that the Staehelin record establishes that on June 2, 1980, the MAB's imported into the United States did bind to antigenic determinants of human interferon- α and, thus, Staehelin has established an actual reduction to practice in the United States no later than June 2, 1980. However, since an actual reduction to practice on June 2, 1980 is subsequent to the filing date of Secher's British I priority application, Staehelin must show that it was reasonably diligent in the United States from a time just prior to Secher's entry in the field, that is, April 11, 1980, up to the time of its actual reduction to practice in June 1980 in order to be awarded priority for the subject matter of the count, *Jepson v. Egly; Hull v. Davenport; Wilson v. Sherts, supra.*

DILIGENCE

[8] Where diligence is involved in the determination of priority, each case rests and must be decided on its own facts, taking into consideration all of the surrounding circumstances. *Wilson v. Sherts, supra.* The evidence relied on to show "reasonable diligence" must ordinarily be directed to reduction to practice of the invention of the counts in issue. *Naber v. Cricchi, 567 F.2d 382, 196 USPQ 294 (CCPA 1977).* The party chargeable with diligence must account for the entire period during which diligence is required, *Gould v. Schawlow, supra*, or acceptable excuses or reasons for failure to take action must be presented.

Hull v. Davenport, supra. Testimonial evidence by the inventor or inventors must be adequately corroborated. *Gould v. Schawlow, supra.* If documentary evidence is relied on to establish reasonable diligence, it must show specific acts at specific times directed at a reduction to practice of the invention of the count. *Naber v. Cricchi, supra.* Activities abroad will not be considered for the purposes of establishing diligence in reducing an invention to practice. 35 USC 104; *Wilson v. Sherts, supra.*

Here, the critical time period in question is from just prior to Secher's entry in the field on April 11, 1980 up to Staehelin's actual reduction to practice on June 2, 1980. The Staehelin record, brief and reply brief are devoid of any evidence of any activity in this country by the inventors or any activity on their behalf in this country towards a reduction to practice of the invention of the count. Quite the contrary, the only evidence of any activity by the inventors during the critical time period in question may be found at StaR, page 18, ¶41, wherein Dr. Staehelin testified that the inventors:

developed in Basle during the period April 1 through May 31, 1980 a procedure for radiolabeling the monoclonal antibodies produced in Exhibit 16 with ^{125}I in order to use them in radioimmunoassay for determining the presence and amount of leukocyte interferon. (emphasis added)

That is, all the inventors were in Switzerland during almost the entire critical time period and could not have been "diligent" within the meaning of 35 USC 104 and the well-settled cases interpreting the statute. See also the corresponding statement at StaB, page 14, first full paragraph.

Staehelin's pronouncement at StaB, page 47, lines 23 and 24 to the effect that from April 7, 1980:

... there was diligence from that time to the reduction to practice on May 22, 1980, does not satisfy Staehelin's burden of establishing diligence by corroborated evidence of the inventors' activity in this country towards a reduction to practice of the invention of the count. Indeed, it appears from all the evidence in this interference that the entirety of Staehelin's work prior to introduction into the United States of the samples of the MAB's produced in Switzerland was, in fact, performed outside this country in Switzerland. The law is clear that such activity may not be relied on to establish a date of invention. 35 USC 104. Accordingly, we conclude that Staehelin has not met its burden of persuasion in proving priority of invention of the subject matter of the count.

ISSUE 6)

In light of our decision as set forth fully above, we consider Secher's motion to suppress under 37 CFR 1.656(h) to be moot. The motion is *dismissed*.

JUDGMENT

David S Secher and Derek C. Burke, the senior party, are entitled to their patent containing claims 1 through 7 corresponding to the count. Additionally, Theophil Staehelin, Christian Stahali and Vicenzo Miggiano are not entitled to a patent containing claims 10 through 12, 14, 16 through 21 and 23 through 25 of their application corresponding to the count.

District Court, N.D. Illinois

American Dental Association Health Foundation v. Bisco Inc.

No. 91 C 8035

Decided June 11, 1992

PATENTS

1. Practice and procedure in Patent and Trademark Office — Prosecution — Filing date (§110.0906)

Patentability/Validity — Anticipation — Prior publication (§115.0705)

Patent infringement plaintiff has demonstrated likelihood of success of demonstrating that patent in suit is entitled, under 35 USC 120, to filing date of its parent patent, and that thus patent is not anticipated by article which was published less than one year before that date.

2. Patentability/Validity — Specification — Enablement (§115.1105)

Accused infringer has failed to demonstrate that patent in suit, for method of adhesively bonding materials used to repair teeth, is invalid pursuant to 35 USC 112 for lack of enablement, since defendant has failed to demonstrate even one compound that falls within scope of claim limitation and that is inoperative, since no evidence demonstrates that three licensees of patent had difficulty identifying appropriate compounds for invention, and since language which defendant contends violates Section 112 was specifically suggested for inclusion by Patent and Trademark Office.

3. Infringement — Literal infringement (§120.05)

Patent infringement plaintiff has demonstrated likelihood of success of demonstrating that its patent for method of adhesively bonding materials used to repair teeth is infringed by accused dental restorative kit, in view of defendant's failure to rebut plaintiff's clear showing that kit directly infringes patent claim which calls for separate containers for each compound.

REMEDIES

4. Non-monetary and injunctive — Equitable relief — Preliminary injunctions — Patents (§505.0707.07)

Showing, by non-profit foundation that uses royalties from its inventions to fund future dental research, that it is losing royalty income both from alleged infringer's sale of its dental restorative kit and from its licensees' threats to suspend royalty payments, and that such lost income hinders its research efforts, constitutes sufficient showing of irreparable harm to warrant issuance of preliminary injunction, nor is such relief precluded by foundation's delay, since such delay was due to its good faith decision to seek settlement of lawsuit; public interest also favors injunction, since such relief will prevent foundation from having to restrict its research efforts, and since public will not be deprived of dental restorative kits, in view of ability of foundation's licensees to satisfy market's demand for product.

Particular patents — Chemical — Dental repair

4,659,751, Bowen, simplified method for obtaining strong adhesive bonding of composites to dentin, enamel, and other substrates, preliminary injunction issued.

Action by American Dental Association Health Foundation against Bisco Inc. and Byoung Suh for patent infringement. On plaintiff's motion for a preliminary injunction. Motion granted.

Allegretti & Witcoff, Ltd. (Jon O. Nelson, Edward W. Remus, and Barbara A. Heaphy, of counsel), Chicago, Ill., for plaintiff.

Marshall, O'Toole, Gerstein, Murray & Bicknell (Basil P. Mann, Richard A. Schnurr, and Christine A. Dudzik, of counsel), Chicago, for defendants.

Kocoras, J.

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